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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,326	03/07/2006	Zhengbin Yao	TNX1001	7572

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,326	YAO ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-4, drawn to a purified polypeptide, wherein said polypeptide comprises an amino acid sequence of SEQ ID NO:2.

Group II, Claims 1-2 and 5-7, drawn to an isolated antibody.

Group III, Claims 8-11, drawn to an isolated polynucleotide, a host cell comprising said isolated polynucleotide.

Group IV, Claims 12, drawn to a method for identifying NFAT activating receptor agonists and antagonists.

Group V, Claim 13, drawn to a screening method for determining whether pharmaceuticals are likely to cause undesirable side effects associated with cytokine and cellular receptor production.

Group VI, Claims 14-16, drawn to a method for affecting the expression of a cellular NFAT activating receptor.

Group VII, Claims 17-18, drawn to a method for diagnosing the predisposition of a patient to develope disease caused by the unregulated expression of cytokines.

Group VIII, Claims 19-20, drawn to a method for preventing or treating NFAT protein-mediated diseases in a mammal.

Group IX, Claim 21, drawn to a method for producing an antibody that binds to NFAT activating receptors.

Group X, Claims 22-23, drawn to an antibody that binds to NFAT activating receptors.

Group XI, Claim 24, drawn to a diagnostic method for detecting NFAT activating receptors expressed in cells.

Group XII, Claims 25-26, drawn to a method for isolating and purifying NFAT activating receptors from recombinant cell culture.

Group XIII, Claims 27-29, drawn to a method for inducing tolerance in a mammal that may experience unwanted immune response.

Group XIV, Claim 30, drawn to a transgenic knock-out animal whose genome comprises a heterozygous or homozygous disruption in its endogenous NFAT activating receptor gene.

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c). "

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application:

Groups I-III, X and XIV are drawn to distinctly different products that perform distinctly different functions, and are independent and mutually exclusive from each other. The special technical feature of Group I is a purified polypeptide. The instantly recited genus of polypeptides is enormous for reasonably embracing polypeptides that are diverse in amino acid sequence and possess distinctly different functions, as indicated by the terms "variant" and "fragment", as demonstrated by the recitation of Claim 2, wherein the polypeptide(s) may be an agonist or antagonist, inhibiting or activating the expression of activity of the NFAT receptor. *A priori*, there is no requirement that the "variant" or "fragment" of SEQ ID NO:2 possess the same activity as the polypeptide consisting of the amino acid sequence of SEQ ID NO:2. The special technical feature of Group II is an antibody that is an agonist or antagonist. The special technical feature of Group X is also an antibody. However, the Group III antibody possesses a function that is not recited for the Group X antibody, specifically agonist or antagonist activities on the NFAT receptor. The special technical feature of Group III is a polynucleotide comprising the nucleic acid sequence of SEQ ID NO:1. Group III is separable from the polypeptide of Group I because the amino acid sequence of SEQ IDNO:2 does not necessarily require the nucleotide sequence of SEQ ID NO:1 and not all of the polypeptides of Group I require the nucleotide sequence of SEQ ID NO:1. The special technical feature of Group XIV is a transgenic animal that possesses none of the Groups I-III and X products, as the transgenic animal is comprises a gene knock-out of the NFAT activating receptor.

Groups IV-IX and XI-XIII are drawn to different methods such that each method requires different process steps, requires the use of different reagents, has different objectives, and does not share a special technical feature. The special technical features of the respective Groups IV-IX and XI-XIII inventions are method steps that do not require the Groups I-III, X and XIV products. Rather, the Group IV method determines whether a compound binds to a receptor, the Group V method determines causes a change in cytokine production, the Group VI method interferes with the transcription or translation of the NFAT activating receptor, the Groups VII and XI methods recite steps of determining the expression levels of NFAT receptors, the Group VIII method recites steps of treating disease in a patient, the Group IX method results in the generation of an antibody, the Group XII method yields purified NFAT polypeptides, and the Group XIII method results in inducing tolerance in a mammal experiencing unwanted immune responses.

A search for a polypeptide having agonist activity towards the NFAT activating receptor would not be co-extensive with a search for a transgenic animal. Further, a reference rendering an antibody that binds the NFAT activating receptor as anticipated or obvious over the prior art would not necessarily also render a nucleic acid encoding an NFAT activating receptor antagonist as anticipated or obvious over the prior art. Similarly, a finding that a method for blocking or modulating the expression of a cellular NFAT activating receptor was novel and unobvious over the prior art would not necessarily extend to a finding that a method for diagnosing the predisposition of a patient to develop disease was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

3. **Should Applicant elect any of Groups I-III, further restriction is required under 35 U.S.C. 121 and 372.** According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have

a common property or activity. This application contains claims directed to more than one species of amino acids and polynucleotides.

Although the chemical compounds are a common structure in that they are nucleic acids (Group III), are all proteins (Group I) or all antibodies (Group II), the compounds are not regarded as being of similar nature because all of the alternatives do not share a common property or activity. Each of the nucleic acids consists of a unique nucleotide sequence, has a distinct melting temperature and a distinct specificity of hybridization. Each of the nucleic acids also encodes for a protein having a distinct amino acid sequence and a distinct biological activity, to wit, an agonist or antagonist. Similarly, each of the antibodies consists of a distinct amino acid sequence and has a different binding specificity.

In response to the restriction requirement regarding Group I, Applicant must further elect a single polypeptide selected from the group consisting of the polypeptides recited in Claims 1, 3 and 4, specifically:

i) the amino acid sequence of SEQ ID NO:2,

ii) a variant of amino acid sequence of SEQ ID NO:2,

iii) a fragment of amino acid sequence of SEQ ID NO:2,

iv) the amino acid sequence encoded by the polynucleotide of SEQ ID NO:1,

v) the amino acid sequence encoded by a variant of SEQ ID NO:1,

vi) the amino acid sequence encoded by a fragment of SEQ ID NO:1,

vii) soluble forms of NFAT activating receptors,

viii) soluble NFAT extracellular domains,

ix) amino acids 43 to 150 of SEQ ID NO:2, or

x) an antagonist fragment of an explicitly elected preceding (i-ix) polypeptide.

In response to the restriction requirement regarding Group II, Applicant must further elect a single antibody from the list consisting of antibodies recited in Claim 6.

In response to the restriction requirement regarding Group III, Applicant must further elect a single nucleic acid selected from the group consisting of nucleic acids recited in Claims 8 and 9, specifically:

i) the polynucleotide of SEQ ID NO:1,

ii) a variant of SEQ ID NO:1,

iii) a fragment of SEQ ID NO:1,

iv) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2,

v) a nucleotide sequence that encodes a variant of amino acid sequence of SEQ ID NO:2,

vi) a nucleotide sequence that encodes a fragment of amino acid sequence of SEQ ID NO:2

vii) a nucleotide sequence encoding amino acids 43 to 150 of SEQ ID NO:2, or

viii) a nucleotide sequence encoding an antagonist fragment.

In response to the restriction requirement for Groups I-III, Applicant must further elect a single function and action attributed to the polypeptide (Group I), antibody (Group II) and polypeptide encoded by the nucleic acid (Group III), specifically one each of A, B and C below, wherein the polypeptide:

A

i) is an NFAT receptor agonist, or

ii) is an NFAT receptor antagonist.

B

i) inhibits, or

ii) activates.

C

i) expression of the NFAT receptor, or

ii) action of the NFAT receptor.

A search for a variant of SEQ ID NO:2 would not be co-extensive with a search for an antibody that is an NFAT activating receptor agonist. Further, a reference rendering a nucleic acid of SEQ ID NO:1 as anticipated or obvious over the prior art would not necessarily also render an antagonist fragment of amino acids 43 to 150 of SEQ ID NO:2 as anticipated or

obvious over the prior art. Similarly, a finding that a bispecific antagonist antibody that is an NFAT activating receptor agonist was novel and unobvious over the prior art would not necessarily extend to a finding that a heteroconjugate antibody that is an NFAT activating receptor antagonist was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

It is further noted that this is a restriction requirement and should not be construed as an election of species.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Q. JANICE LI, M.D.
PRIMARY EXAMINER